

as the abstract of the PCT application of which this application claims priority.

Issue Under Election/Restriction

Applicants acknowledge the invention of group I, claims 1 and 3-11 were elected with traverse in a telephone conversation on December 4, 2001. Applicants understand that claims 13-16 have been withdrawn from consideration.

Applicants respectfully request the Examiner to reconsider her requirement of a restriction. Applicants disagree that the embodiments of Groups I-III fail to have common special feature. The special technical feature is the novel androgens of formula I. Applicants will explain below why the cited prior art fails to render the compounds anticipated or obviousness; thus, claims 1 and 3-11 are patentable. Therefore, if claims 1 and 3-11 are patentable, logic dictates that claims 13-16 should be allowable.

Specification

Applicants have submitted an Abstract of the Disclosure on a separate sheet to meet the requirements of the USPTO.

Priority

Applicants acknowledge that the Examiner has reported that SOME of the certified copies of the priority documents have been received. Applicants respectfully request the Examiner to identify what copies are present in the file and what copies are not present.

Issue Under 35 U.S.C. §102(b)

Claims 1, 3, 8 and 9 stand rejected under 35 U.S.C. §102(b) as being anticipated AN-CA62:1704c, HCAOLD and AN-CA61:4426h, CAOLD (abstract of BE 623844). Applicants submit the patentable distinctions between the cited prior art and the present invention.

Distinctions Between the Present Invention and AN-CA62:1704c and AN-CA61:4426h

The Examiner has identified compounds of registry numbers 95171-22-5 and 95366-80-6 as being specific examples of interest from the Chemical Abstract references. Both Chemical Abstract reference are abstracts of Belgian Patent No. 623844 (Smith '844). Applicants have attained Smith '844 and discovered that the compounds in the Chemical Abstract are based on a mistake

made the transcribers at Chemical Abstracts. Therefore, the Chemical Abstract references do not have enabling disclosures and the compounds referenced have not been synthesized in Smith '844.

Smith '844 discloses 17-substituted steroids without a substituent on position 7. While Smith '844 is in French, a skilled artisan would recognize that on page 2, the structural names fail to disclose a steroid with substitution at the 7 position. Applicants submit that for the two compounds cited in the abstract and by the Examiner, the Chemical Abstract transcriber apparently dropped off the digit 1 before the 7; thus changing the compound from a 17 substituted steroid to a 7 substituted steroid.

Thus, the formulae disclosed in the Chemical Abstracts are based only on an erroneous name and the underlying reference, Smith '844, fails to provide an enabling disclosure for 7-substituted steroid as set forth in the present invention.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Clearly, Smith '844 fails to disclose each and every element of the present invention as set

forth in the claims. Applicants have attached a copy of Smith '844 for the Examiner's review.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

Issue Under 35 U.S.C. §103(a)

Claims 1, and 3-11 stand rejected under 35 U.S.C. §103(a) as being obvious over GB '974 (GB 1298974). Applicants respectfully submit that patentable distinction exist between the present invention and the cited prior art.

Distinctions Between the Present invention and GB '974

GB '974 discloses 7 $\beta$ -alkyl steroids and the preparation thereof. GB '974 discloses that the 7 position is substituted with an alkyl group, wherein the alkyl group has from 1 to 10 carbon atoms. However, GB' 974 clearly discloses that the 7 $\beta$  configuration is preferred along with an alkyl substitution at the 17 position.

GB '974 fails to disclose or suggest derivatives of 7 $\alpha$ -methyl-19-nortestosterone as set forth in the present claims. "A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure

indicates a preference leading away from the claimed compounds." In re Baird, 16 F.3d 380, 383, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994). GB '974 only generally discloses compounds with an alkyl substitution at the 7 position and indicates a preference that leads away from the present compounds by only suggesting "7 $\beta$ -alkylestrones." Applicants assert that a skilled artisan would not have a reasonable expectation of success of making the present compounds and achieving greater stability in vivo, as demonstrated by the longer half-life in the presence of hepatocytes. See Table on page 26.

The Examiner must present a *prima facie* case of obviousness consisting of motivation or suggestion to modify or combine references such that one of ordinary skill in the art has a reasonable expectation of success of using the present invention. "Obviousness can only be established by combining or modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP 2143.01, citing In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). As stated above GB '947 fails to provide motivation to a skilled artisan to modify the disclosure to make the present invention as described in the claims. Therefore, a skilled artisan would not have a reasonable

expectation of success of making the resent invention. Therefore, Applicants submit that a *prima facie* case of obviousness has not been established.

Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection.

Conclusion

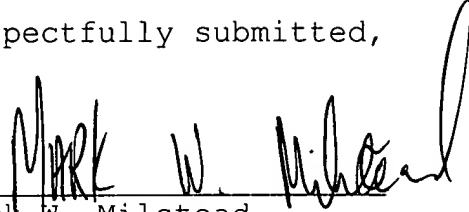
Applicants submit that every issue raised by the outstanding Office Action has been addressed and rebutted. Therefore, the present claims define patentable subject matter and are in condition for allowance.

Should the Examiner believe that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone Applicants' Attorney at the number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any

additional fees required under 37 C.F.R. §§ 1.16 or 1.17;  
particularly, extension of time fees.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark W. Milstead", written over a horizontal line.

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Enclosure: Abstract of the Disclosure  
BE 623844